UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, Plaintiff, v. PAR PHARMACEUTICAL, INC., PAR PHARMACEUTICAL COMPANIES, INC., and TEVA PHARMACEUTICALS USA, INC., Defendants.	**C.A. No. 17-3159 (ES)(MAH)** *Electronically Filed*
CELGENE CORPORATION, Plaintiff, v. HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, HETERO DRUGS LIMITED, HETERO USA, INC., AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., AUROLIFE PHARMA LLC, EUGIA PHARMA SPECIALTIES LIMITED, APOTEX INC., APOTEX CORP., MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN, N.V., and BRECKENRIDGE PHARMACEUTICAL, INC., Defendants.	**C.A. No. 17-3387 (ES)(MAH)** *Electronically Filed*

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiff Celgene Corporation ("Celgene") and Defendants Breckenridge Pharmaceutical, Inc. ("Breckenridge"), Teva Pharmaceuticals USA, Inc. ("Teva"), Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited (together, "Aurobindo"), Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (together,

"Mylan"), Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (together, "Hetero"), Apotex Inc., and Apotex Corp. (together "Apotex") (collectively, "Defendants") hereby submit their Joint Claim Construction and Prehearing Statement in accordance with Local Patent Rule 4.3.

I. BACKGROUND

These cases arise out of the Defendants' filing of their respective Abbreviated New Drug Applications ("ANDAs") Nos. 210236 ("Hetero's ANDA"), 210249 ("Aurobindo's ANDA"), 210164 ("Apotex's ANDA"), 210275 ("Mylan's ANDA"), 209956 ("Teva's ANDA"), and 210111 ("Breckenridge's ANDA"), with the U.S. Food and Drug Administration ("FDA"), seeking approval to market generic versions of Celgene's Pomalyst® drug products. The active pharmaceutical ingredient in Pomalyst® is pomalidomide. Celgene alleges, among other things, that Defendants' submission of their respective ANDAs constitutes infringement of certain claims of United States Patent Nos. 8,198,262 ("the '262 patent"), 8,673,939 ("the '939 patent), 8,735,428 ("the '428 patent"), 8,828,427 ("the '427 patent"), 6,315,720 ("the '720 patent"), 6,561,977 ("the '977 patent"), 6,755,784 ("the '784 patent"), 8,315,886 ("the '886 patent"), and 8,626,531 ("the '531 patent") owned by Celgene (collectively, "the patents-in-suit") under 35 U.S.C. § 271(e)(2).[1] Defendants allege, among other things, that the asserted claims are invalid and/or not infringed.

Pursuant to Local Patent Rules 4.2(a)-(b), on June 15, 2018, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their proposed Preliminary Constructions. Pursuant to Local Patent Rule 4.2(c), on July 18, 2018, the parties identified all intrinsic and extrinsic evidence that each party intends to rely

[1] The '720 patent, the '977 patent, the '784 patent, the '886 patent, and the '531 patent are not asserted against Teva and Mylan.

upon to oppose any other party's proposed construction. Pursuant to Local Patent Rule 4.2(d), on July 31, 2018 counsel for all parties met and conferred for the purposes of narrowing the issues and preparation of the Joint Claim Construction and Prehearing Statement.

II. CONSTRUCTION OF PATENT TERMS

A. Agreed-Upon Claim Constructions

Pursuant to Local Patent Rule 4.3(a), the parties identify the following terms and phrases on which the parties agree. To the extent that claim terms are used repeatedly throughout a patent or family of patents, any constructions of such terms carry the same meaning throughout a patent or family of patents. The parties agree that, unless otherwise identified below, the terms in the asserted claims do not require construction.

Term	Patent(s)	Definition
"retrieved"	'720 patent, claims 1-21, 23-32 '977 patent, claims 1-23, 25-34 '886, claims 1-7	actively gotten or obtained
"received"	'784 patent, claims 1-23. 25-34 '531 patent, claims 1-40	passively taken into possession
"risk groups"	'531 patent, claims 1-40	classifications based upon the chance that an adverse side effect may occur

B. Disputed Claim Terms

Pursuant to Local Patent Rule 4.3(b), attached hereto as Exhibit A is a claim chart identifying the claim terms in dispute, the parties' proposed constructions, and the evidence (both intrinsic and extrinsic) that each party intends to rely on in support of its proposed construction or to oppose the other party's proposed construction. To the extent that claim terms are used repeatedly throughout a patent or family of patents, any construction of such term

carries the same meaning throughout a patent or family of patents. Included in the below table is a summary of the remaining disputed claim terms and their corresponding asserted claim numbers:

Term(s)	Patent(s)
"A method of treating multiple myeloma"	'262 patent claims 1-2, 4-16, 18-27, 29 '939 patent claims 1-14, 16-35 '428 patent claims 1-27
"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof"	'262 patent claim 1-2, 4-16, 18-27, 29 '939 patent claim 1-14, 16-25 '428 patent claim 1-21
"about 1 mg to about 5 mg of a compound having the formula [of pomalidomide] or a solvate thereof"	'939 patent claim 26-35 '428 patent claim 22-27
"pregelatinized starch at an amount of [x] mg" "sodium stearyl fumarate at an amount of [x] mg" "An oral dosage form in the form of a capsule which weighs [x] mg"	'427 patent claims 3-10
"total weight of the composition"	'427 patent claims 3-10
"computer readable storage medium"	'720 patent claims 1-21, 23-32 '977 patent claims 1-23, 25-34 '784 patent claims 1-23, 25-34 '886 patent claims 1-7
"prescription approval code"	'720 patent claims 1-21, 23-32 '977 patent claims 1-23, 25-34 '784 patent claims 1-23, 25-34 '886 patent claims 1-7 '531 patent claims 1-40
"computer readable medium"	'531 patent claims 1-40
"a generator configured to generate a prescription	'531 patent claims 1-20

approval code"	

C. Claim Terms Whose Construction Will Be Most Significant

Pursuant to L. Pat. R. 4.3(c), Plaintiff contends that none of the terms' "construction will be most significant to the resolution of the case" and that none of the terms' "construction will be case or claim dispositive or substantially conducive to promoting settlement."

Defendants contend that the construction of the terms in the '427 patent are most significant or dispositive because Defendants believe that their construction of at least terms containing "at an amount of [x] mg" supports their non-infringement arguments.

D. Anticipated Length Of Time Necessary For The Claim Construction Hearing

Pursuant to Local Patent Rule 4.3(d), the parties anticipate that the Court will be able to conduct a hearing on the meaning of the disputed claim terms in one full day.

E. Identification Of Witnesses For The Claim Construction Hearing

Pursuant to L. Pat. R. 4.3(e), the parties do not currently plan to call any witnesses at the claim construction hearing.

As set forth in Exhibit A, however, Teva, Mylan, Breckenridge, and Aurobindo intend to rely upon expert testimony from Dr. Kinam Park and/or similarly qualified experts that will be submitted to the Court by declaration. Celgene, likewise, may rely upon expert testimony from Dr. Djordje Atanackovic and/or Dr. Steve Little, and/or similarly qualified experts that will be submitted to the Court by declaration.

Dated: August 29, 2018

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Exhibit A

Disputed Claim Terms & Evidence

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
"A method for treating multiple myeloma"	"A method for treating multiple myeloma" is limiting, such that the term requires efficacy in treating multiple myeloma[2] **Evidence**[3,4]	"A method for treating multiple myeloma" is not limiting **Evidence**[6]

[2] Teva, Mylan, Breckenridge, and Aurobindo respectfully submit that Celgene's proposed construction was not disclosed in Celgene's Local Patent Rule 4.2(a) disclosure, as Celgene originally asserted "[n]o construction required" for this claim term. Teva, Mylan, Breckenridge, and Aurobindo thus reserve the right to seek relief from the Court on this issue.

[3] Defendants respectfully submit that much of the evidence Celgene identifies for the [a] method for treating multiple myeloma" term—including certain citations to the intrinsic record and including all of the extrinsic evidence identified—was not disclosed in any of Celgene's Local Patent Rule 4.2(a)-(c) disclosures, in violation of Local Patent Rule 4.3(f). The Parties have met and conferred regarding this issue and are at an impasse. Defendants thus reserve the right to seek relief from the Court on this issue, including an order striking those identifications of evidence not previously disclosed in compliance with the Local Patent Rules, and precluding Celgene from relying on such evidence during claim construction. Defendants also reserve the right to rely on additional evidence not listed in this Joint Claim Construction Statement in opposing Celgene's previously undisclosed construction and evidence.

[4] Defendants explained during the parties' July 31, 2018 Local Patent Rule 4.1(b) meet and confer—which did not take place until ***after all exchanges under L. Pat. R. 4.2(a)-(c)***—that, by arguing "[a] method for treating multiple myeloma" is not limiting, they are arguing that the method of treatment claim does not require efficacious treatment. Defendants further requested that Celgene clarify that its position is that "a method of treating multiple myeloma" is limiting and specifically whether Celgene means that the claim requires efficacy in treating multiple myeloma. Celgene did just that in response to Defendants' request. Defendants' attempt to now argue that Celgene violated any Rules (in footnotes 2 and 3 above) lacks merit. The purpose of the Local Patent Rule 4.1(b) meet and confer is to "facilitat[e] the ultimate preparation of a Joint Claim Construction and Prehearing Statement." The Local Patent Rules are designed to allow for an iterative process for claim construction. That purpose would be defeated under Defendants' position. Furthermore, Celgene expressly stated in its earlier disclosures that it reserved the right to supplement or change its proposed constructions, the evidence supporting its constructions, and the evidence opposing Defendants' proposed constructions. Defendants never objected. In fact, Defendants included the same reservation of rights in their exchanges—specifically calling out the need for

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	Intrinsic Evidence: • U.S. Patent No. 8,198,262 generally, including (without limitation) at Figure 1, 2:18-3:37, 3:41-4:52, 9:57-10-56; 11:8-58; 16:7-67, 17-52-56; 18:24-29, 19:34-37, 21:15-25, 22:26-57, 23:33-24:61, 32:45-36:41, 37:57-38:6.[5] • File History of U.S. Patent No. 8,198,262 • File History of U.S. Patent No. 8,673,939 • File History of U.S. Patent No. 8,735,428 **Extrinsic Evidence:** • Weber, et al., Abstract #719, T*halidomide with dexamethasone for resistant multiple myeloma*, Blood, 96(11):167a (2000). • Aviles, et al., *Dexamethasone, all trans retinoic acid and interferon alpha 2a in patients with refractory multiple myeloma*, Cancer Biotherapy & Radiopharmaceuticals, 14(1):23-26 (1999). • Dimopoulos, et al., *Thalidomide and*	**Claims:** • '262 patent, claims 1–29. • '939 patent, claims 1–35. • '428 patent, claims 1–27. **Specification:**[7] • The '262 patent, *see, e.g.*, Figure 1, 2:14-17; 2:48-64; 2:65-66; 3:8-14; 3:41-56; 3:53-4:3; 4:23-29; 4:34-40; 16:8-29; 17:52-18:4; 18:12-35; 21:60-22:57; 23:4-16; 24:5-62; 31:15-44; 33:1-36:41; 37:42-38:13; 38:16-40:23. • The '939 patent, *see, e.g.*, portions of the '939 patent corresponding to the portions of the '262 patent cited, *supra*; 38:65-40:57. • The '428 patent, *see, e.g.*, portions of the '428 patent corresponding to the portions of the '262 patent cited, *supra*; 39:1-40:47. **Prosecution History:**

supplementation "***following further meet-and-confers***." And, as noted below, Defendants did, in fact, cite to new evidence for the first time after the L. Pat. R. 4.2(a)-(c) exchanges. Thus, Defendants' accusations against Celgene are meritless.

[6] Where exemplary pages are provided in this Joint Claim Construction Statement, Defendants may rely upon any and all other pages included in the below-identified sources. By identifying evidence, Defendants, do not concede that such evidence is necessary to construe the disputed claim term.

[5] U.S. Patent Nos. 8,198,262, 8,673,939 and 8,735,428 share a common specification. For convenience, citations to the specification are listed only for the '262 patent. Celgene relies on corresponding citations to the specifications of the '939 and the '428 patents.

[7] The '262, '939, and '428 patents are related patents that share a common specification. For convenience, cites to the specification are listed only for the '262 patent. Defendants rely on corresponding citations to the specifications of the other '939, and '428 patents.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	dexamethasone combination for refractory multiple myeloma, Ann Oncology, 12:991- 995 (2001). • Richardson, et al., Abstract #3225-3226, *A phase 1 study of oral CC5013, an immunomodulatory thalidomide (Thal) derivative, in patients with relapsed and refractory multiple myeloma (MM)*, Blood, 98:775a (2001). • Sydney E. Salmon et al., *Plasma Cell Neoplasms in* CANCER PRINCIPLES & PRACTICE OF ONCOLOGY 2344 (5th ed. 1997). • Weber, et al., Abstract #2686, *Thalidomide Alone or With Dexamethasone for Multiple Myeloma*, Blood, 94(1):604a (1999). • Oken, et al., *Comparison of melphalan and prednisone with vincristine, carmustine, melphalan, cyclophosphamide, and prednisone in the treatment of multiple myeloma*, Cancer, 79:1561-1567 (1997). • Kyle, et al., *Therapeutic Application of thalidomide in Multiple Myeloma*, Semin. Oncol., 28(6):583-587 (2001). • Zangari, M., et al., *Thrombogenic activity of doxorubicin in myeloma patients receiving thalidomide: implications for therapy*, Blood, 100:1168-1171 (2002). • Rajkumar, et al., Abstract #723, *A Phase II Trial*	• '262 patent, *see, e.g.*, Original Application at Claims (CELPOM00000147-152); August 19, 2008 Preliminary Amendment (CELPOM00000157-164); June 24, 2010 Office Action (CELPOM00000190-204); December 23, 2010 Amendment and Response (CELPOM00000216-229); August 9, 2011 Office Action (CELPOM00000274-284); December 20, 2011 Amendment and Response (CELPOM00000298-326); March 6, 2012 Applicant-Initialed Interview Summary (CELPOM00000335); March 15, 2012 Response and Statement of Interview Summary (CELPOM00000337-343); Notice of Allowance (CELPOM00000348); Notice of Allowability (CELPOM00000352-55); Application for Extension of Patent Term under 35 U.S.C. § 156 (CELPOM00000719-820). • '939 patent, *see, e.g.*, Original Application at Claims (CELPOM00000903-08); March 1, 2013 Preliminary Amendment (CELPOM00000946-954); July 8, 2013 Office Action (CELPOM00001011-024); October 8, 2013 Response (CELPOM00001068-92); October 9, 2013 Applicant-Initiated Interview Summary (CELPOM00001112-13); November 6, 2013 Response to Applicant-Initiated Interview Summary (CELPOM00001115-6); Notice of Allowance (CELPOM00001119-20) • '428 patent, *see, e.g.*, Original Application at

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	of Thalidomide in the Treatment of Relapsed Multiple Myeloma (MM) with Laboratory Correlative Studies, Blood, 96(11):168a (2000). • Durie, B.G.M., and Stepan, D.E., *Efficacy of low dose thalidomide in multiple myeloma*, Electronic Journal of Oncology, 1:1-8 (2000). • Celgene may rely on the expert opinion from Dr. Djordje Atanackovic, or a similarly qualified expert regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	Claims (CELPOM00001204-09); March 1, 2013, Preliminary Amendment (CELPOM00001258-65); July 9, 2013, Office Action (CELPOM00001321-33); October 9, 2013 Response (CELPOM00001370-93); October 17, 2013 Applicant-Initiated Interview Summary (CELPOM00001413-15); November 6, 2013, Response to Applicant-Initiated Interview Summary (CELPOM00001416-7); Notice of Allowance (CELPOM00001420-1) **Additional Evidence:** [8, 9,10] • Expert testimony from Dr. Kinam Park and/or similarly qualified experts establishing: (1) that a POSA would understand the claims to have Defendants' proposed construction; and/or (2) that a POSA would understand the claims, specification and file history to support Defendants' proposed construction. Such testimony may be provided by an expert qualified in the field of pharmaceutical

[8] For each claim term from the '262, '939. '428 and/or '427 patents in this Joint Claim Construction Statement, the Additional Evidence identified may include intrinsic and/or extrinsic evidence.

[9] For each claim term from the '262, '939, '428 and/or '427 patents in this Joint Claim Construction Statement, Defendants reserve the right to introduce expert testimony from Dr. Kinam Park and/or similarly qualified experts regarding the definition of a person of ordinary skill in the art, and may additionally rely on expert testimony to rebut Plaintiff's proposed meanings, expert testimony, or other evidence offered by Plaintiff in support of its proposed claim constructions, or in opposing Defendants' proposed claim constructions (as disclosed in Teva, Mylan, Breckenridge, and Aurobindo's L. Pat. R. 4.2(a) and (c) statements).

[10] Celgene notes that Defendants introduce the new subjects of proposed expert testimony in footnote 9 for the first time in this submission, further undermining their position regarding the Local Patent Rules and the purpose of the required meet-and-confer process in preparation of this Joint Claim Construction and Prehearing Statement.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		formulation and chemistry and/or in the treatment of multiple myeloma or related conditions. **Alternative Proposal & Evidence of Apotex and Hetero:** If "A method for treating multiple myeloma" is found to be limiting, then it should be construed as: "A method of administering pomalidomide, or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof, after the onset of symptoms of multiple myeloma." **Evidence** • The '262 patent, *see, e.g.*, Figure 1, 2:14-17; 2:48-64; 2:65-66; 3:8-14; 3:41-56; 3:53 – 4:3; 4:23-29; 4:34-40; 16:8-29; 17:52 – 18:4; 18:12-35; 21:60 – 22:57; 23:4-16; 24:5-62; 31:15-44; 33:1 – 36:41; 37:42 – 38:13; 38:16 – 40:23 • The '939 patent, *see, e.g.*, portions of the '939 patent corresponding to the portions of the '262 patent cited, *supra*; 38:65 – 40:57 • The '428 patent, *see, e.g.*, portions of the '428 patent corresponding to the portions of the '262 patent cited, *supra*; 39:1 – 40:47 • The prosecution history of the '262 patent, *see, e.g.*, Original Application at Claims (CELPOM00000147-152); August 19, 2008 Preliminary Amendment (CELPOM00000157-164); June 24, 2010 Office Action

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		(CELPOM00000190-204); December 23, 2010 Amendment and Response (CELPOM00000216-229); August 9, 2011 Office Action (CELPOM00000274-284); December 20, 2011 Amendment and Response (CELPOM00000298-326); March 6, 2012 Applicant-Initialed Interview Summary (CELPOM00000335); March 15, 2012 Response and Statement of Interview Summary (CELPOM00000337-343); Notice of Allowance (CELPOM00000348); Notice of Allowability (CELPOM00000352-55); Application for Extension of Patent Term under 35 U.S.C. § 156 (CELPOM00000719-820) • The prosecution history of the '939 patent, *see, e.g.*, Original Application at Claims (CELPOM00000903-08); March 1, 2013 Preliminary Amendment (CELPOM00000946-954); July 8, 2013 Office Action (CELOPOM00001011-024); October 8, 2013 Response (CELPOM00001068-92); October 9, 2013 Applicant-Initiated Interview Summary (CELPOM00001112-13); November 6, 2013 Response to Applicant-Initiated Interview Summary (CELPOM00001115-6); Notice of Allowance (CELPOM00001119-20) • The prosecution history of the '428 patent, *see, e.g.*, Original Application at Claims (CELPOM00001204-09); March 1, 2013 Preliminary Amendment (CELPOM00001258-

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		65); July 9, 2013 Office Action (CELPOM00001321-33); October 9, 2013 Response (CELPOM00001370-93); October 17, 2013 Applicant-Initiated Interview Summary (CELPOM00001413-15); November 6, 2013 Response to Applicant-Initiated Interview Summary (CELPOM00001416-7); Notice of Allowance (CELPOM00001420-1) • Prior art not previously before the United States Patent and Trademark Office cited in Defendants' Joint Invalidity Contentions for the '262, '939, and '428 patents • Expert opinions about the level of ordinary skill in the art, the state of the relevant art, the meaning of "A method for treating multiple myeloma" as used in the asserted claims to a person of ordinary skill in the art at the time of the filing dates of the patents
"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically	"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a pharmaceutically acceptable salt, solvate, or stereoisomer containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"[11,12]	"about 1 mg to 5 mg ... of a compound having the formula [ ] or about 1 mg to 5 mg of a pharmaceutically acceptable salt or solvate of [ ] or about 1 mg to 5 mg of any single stereoisomer of [ ]" **Evidence**

[11] Defendants respectfully submit that Celgene's proposed construction was not disclosed in Celgene's Local Patent Rule 4.2(a) disclosure, as Celgene originally asserted "[n]o construction required" for this claim term. Defendants thus reserve the right to seek relief from the Court on this issue, and may seek to rely on additional evidence not disclosed in this Joint Claim Construction Statement in opposing Celgene's previously undisclosed construction.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
acceptable salt, solvate, or stereoisomer thereof"	**Evidence** **Intrinsic Evidence:** • U.S. Patent No. 8,198,262 generally, including (without limitation) at 5:14-19, 9:57-10:12, 11:8-46, 26:48-27:22, 30:34-36. • File History of U.S. Patent No. 8,198,262 • File History of U.S. Patent No. 8,673,939 • File History of U.S. Patent No. 8,735,428 **Extrinsic Evidence:** • Celgene may rely on the expert opinion from Dr. Atanackovic, Dr. Steve Little, or similarly qualified experts regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary	**Claims:** • '262 Patent, claims 10-13, 18, 20-24, 26, 28 • '939 Patent, claims 8-11, 12, 17, 28-29 • '428 Patent, claims 8-11, 15, 16, 24 **Specification:** • '262 patent at 4:53-60, 5:14-28, 7:20-40, 8:45-63, 9:57-10:12, 10:57-11 :46, 18:5-11, 23:20-25, 24:62-25:3, 26:48- 27:8, 30:44-47 **Prosecution History:** • '428 patent, October 9, 2013 Response, *see, e.g.* at 2- 5, 8-9 • '939 patent, October 8, 2013 Response, *see, e.g.* at 2- 5, 9-10 • '262 patent, August 19, 2008 Preliminary

[12] Defendants requested during the parties' July 31, 2018 Local Patent Rule 4.1(b) meet and confer—which did not take place until ***after all exchanges under L. Pat. R. 4.2(a)-(c)***—that Celgene clarify what its position was with respect to this term. Celgene did just that in response to Defendants' request. Defendants' attempt to argue that Celgene violated any Rules (in footnote 11 above) lacks merit. The purpose of the Local Patent Rule 4.1(b) meet and confer is to "facilitat[e] the ultimate preparation of a Joint Claim Construction and Prehearing Statement." The Local Patent Rules are designed to allow for an iterative process for claim construction. That purpose would be defeated under Defendants' position. Furthermore, Celgene expressly stated in its earlier disclosures that it reserved the right to supplement or change its proposed constructions, the evidence supporting its constructions, and the evidence opposing Defendants' proposed constructions. Defendants never objected. In fact, Defendants included the same reservation of rights in their exchanges—specifically calling out the need for supplementation "***following further meet-and-confers***." And, as noted above, Defendants did, in fact, cite to new evidence for the first time after the L. Pat. R. 4.2(a)-(c) exchanges. Thus, Defendants' accusations against Celgene are meritless.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	Amendment, *see, e.g.* at 4-5 • '262 patent, August 9, 2011 Office Action, *see, e.g.* at 6-7 • '262 patent, March 16, 2012 Response, *see, e.g.* at 5 **Additional Evidence:** • U.S. Patent No. 8,828,427, Claims 1, 3, 5, 7, 9, and 11 • United States Pharmacopeia 31, National Formulary 26 (2008) • Pharmaceutical Calculations, 13th Ed. (2010) • Expert testimony from Dr. Kinam Park and/or similarly qualified experts establishing: (1) that a POSA would understand the claims to have Defendants' proposed construction; (2) the impact on a dose based on whether the compound is present as a salt, solvate, or stereoisomer; (3) the standard practice in the field at the relevant time period was to calculate weights of compounds, including salt, solvates, and stereoisomers, taking into account counter ions and solvent molecules; (4) the standard practice in the field at the relevant time period was that compounds may be administered in salt, solvate or stereoisomer form, and/or (5) that a POSA would understand the claims, specification and file history to support Defendants' proposed construction. Such

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		testimony may be provided by an expert qualified in the field of pharmaceutical formulation and chemistry and/or in the treatment of multiple myeloma or related conditions.
"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a solvate thereof"	"about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide] or a solvate containing about 1 mg to about 5 mg per day of a compound having the formula [of pomalidomide]"[13,14] **Evidence** **Intrinsic Evidence:** • U.S. Patent No. 8,735,428 generally, including	"about 1 mg to 5 mg ... of a compound having the formula [ ] or about 1 mg to 5 mg of a solvate of [ ]" **Evidence** **Claims:** • '262 Patent, claims 10-13, 18, 20-24, 26, 28 • '939 Patent, claims 8-11, 12, 17,28- 29

[13] Defendants respectfully submit that Celgene's proposed construction was not disclosed in Celgene's Local Patent Rule 4.2(a) disclosure, as Celgene originally asserted "[n]o construction required" for this claim term. Defendants thus reserve the right to seek relief from the Court on this issue, and may seek to rely on additional evidence not disclosed in this Joint Claim Construction Statement in opposing Celgene's previously undisclosed construction.

[14] Defendants requested during the parties' July 31, 2018 Local Patent Rule 4.1(b) meet and confer—which did not take place until ***after all exchanges under L. Pat. R. 4.2(a)-(c)***—that Celgene clarify what its position was with respect to this term. Celgene did just that in response to Defendants' request. Defendants' attempt to argue that Celgene violated any Rules (in footnote 13 above) lacks merit. The purpose of the Local Patent Rule 4.1(b) meet and confer is to "facilitat[e] the ultimate preparation of a Joint Claim Construction and Prehearing Statement." The Local Patent Rules are designed to allow for an iterative process for claim construction. That purpose would be defeated under Defendants' position. Furthermore, Celgene expressly stated in its earlier disclosures that it reserved the right to supplement or change its proposed constructions, the evidence supporting its constructions, and the evidence opposing Defendants' proposed constructions. Defendants never objected. In fact, Defendants included the same reservation of rights in their exchanges—specifically calling out the need for supplementation "***following further meet-and-confers***." And, as noted above, Defendants did, in fact, cite to new evidence for the first time after the L. Pat. R. 4.2(a)-(c) exchanges. Thus, Defendants' accusations against Celgene are meritless.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	(without limitation) at 5:14-19, 26:48-27:22, 30:34-36 • File History of U.S. Patent No. 8,673,939 • File History of U.S. Patent No. 8,735,428 **Extrinsic Evidence:** • Celgene may rely on the expert opinion from Dr. Atanackovic, Dr. Steve Little, or similarly qualified experts regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	• '428 Patent, claims 8-11, 15, 16, 24 **Specification:** • 4:53-60, 5:14-28, 7:20-40, 8:45-63, 9:57- 10:12, 10:57-11 :46, 18:5- 11, 23:20-25, 24:62- 25:3, 26:48- 27:8, 30:44-47 **Prosecution History:** • '428 patent, October 9, 2013 Response, *see, e.g.* at 2- 5, 8-9 • '939 patent, October 8, 2013 Response, *see, e.g.* at 2- 5, 9-10 • '262 patent, August 19, 2008 Preliminary Amendment, *see, e.g.* at 4-5 • '262 patent, August 9, 2011 Office Action, *see, e.g.* at 6-7 • '262 patent, March 16, 2012 Response, *see, e.g.* at 5 **Additional Evidence:** • U.S. Patent No. 8,828,427, Claims 1, 3, 5, 7, 9, and 11 • United States Pharmacopeia 31, National Formulary 26 (2008) • Pharmaceutical Calculations, 13th Ed. (2010) • Expert testimony from Dr. Kinam Park and/or similarly qualified experts establishing: (1) that a POSA would understand the claims to have

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		Defendants' proposed construction; (2) the impact on a dose based on whether the compound is present as a salt, solvate, or stereoisomer; (3) the standard practice in the field at the relevant time period was to calculate weights of compounds, including salt, solvates, and stereoisomers, taking into account counter ions and solvent molecules; (4) the standard practice in the field at the relevant time period was that compounds may be administered in salt, solvate or stereoisomer form, and/or (5) that a POSA would understand the claims, specification and file history to support Defendants' proposed construction. Such testimony may be provided by an expert qualified in the field of pharmaceutical formulation and chemistry and/or in the treatment of multiple myeloma or related conditions.
"pregelatinized starch at	No construction required[15,16]	**Proposal & Evidence of Teva, Mylan, Breckenridge,**

[15] Teva, Mylan, Breckenridge, and Aurobindo respectfully submit that Celgene has failed to disclose a proposed construction for this term in this Joint Statement or with its Local Patent Rule 4.2(a) disclosure. Teva, Mylan, Breckenridge, and Aurobindo thus reserve the right to seek relief from the Court on this issue, and may seek to preclude Celgene from offering a "plain and ordinary" meaning of the term. To the extent Celgene is able to propose a construction, Teva, Mylan, Breckenridge, and Aurobindo also reserve the right to seek to rely on additional evidence in opposition.

[16] Celgene has not "failed to disclose a proposed construction." Courts, including this one, routinely hold that no construction is required for claim terms. Notably, two Defendants—Apotex and Hetero—agree with Celgene that no construction is required for these terms.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
an amount of [x] mg" "sodium stearyl fumarate at an amount of [x] mg" "An oral dosage form in the form of a capsule which weighs [x] mg"	**Evidence** **Intrinsic Evidence:** • U.S. Patent No. 8,828,427 generally • File History of U.S. Patent No. 8,828,427 **Extrinsic Evidence:** • Celgene may rely on the expert opinion regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	**and Aurobindo:** "[x] mg when rounded off" **Evidence** **Claims ('427 patent):** • Claims 1, 3, 5, 7, 9 and 11 **Specification ('427 patent):** 4:4-14, 6:34-7:25, 8:24-12:14, Examples 1-6 **Prosecution History ('427 Patent):** • U.S. Application No. 12/783,390, May 19, 2010, *see, e.g.* at 44-49 (claims 1, 11, 21, 31, 41, and 51) • Office Action, April 24, 2012, *see, e.g.* at 2-11 • Amendment and Response, August 16, 2012, *see, e.g.* at 3-10 • Office Action, November 15, 2012, *see, e.g.* at 3-15 • Amendment and Response, February 13, 2013, *see, e.g.* at 2-10 • Advisory Action, March 25, 2013, *see, e.g.* at 1-4 • Interview Summary, May 16, 2013 • Supplemental Amendment and Response, June 17, 2013, *see, e.g.* at 2-10; Ex. A (Tutino Decl.) • Notice of Allowability, May 5, 2014, *see, e.g.* at

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		3-4 **Additional Evidence:** • McNally et al. (Patent No. 5,593,696). DEFS_POM_00013798–802 • Remington's Pharmaceutical Sciences, 17th Edition, Published 1985. CELPOM00001657–67 • Zeldis et al. (Pub. No. US 2007/0155791 Al, Published July 5, 2007). CELPOM00001573–623 • United States Pharmacopeia 31, National Formulary 26 (2008). DEFS_POM_00013803–816 • Pharmaceutical Calculations, 13th Ed. (2010). DEFS_POM_00013788–97 • FDA Office of Regulatory Affairs, ORA Lab Manual (2013). DEFS_POM_00013817–842 • Expert testimony from Dr. Kinam Park and/or similarly qualified experts establishing: (1) that a POSA or reasonable competitor would understand the claims to have Defendants' proposed construction; (2) that a POSA or reasonable competitor would understand the claims, specification and file history to support Defendants' proposed construction; and (3) that a POSA or reasonable competitor would understand from the specification and the file history that the claimed invention would not

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		cover compositions lacking sodium stearyl fumurate, compositions having less spray dried mannitol, pregelatinized starch, or total composition weight than the weight amounts actually specifically recited in the claims. Such testimony may be provided by an expert qualified in the field of pharmaceutical formulation and chemistry. **Proposal of Defendants Apotex and Hetero:** No construction necessary.
"total weight of the composition"	No construction required.[17,18] **Evidence** **Intrinsic Evidence:** • U.S. Patent No. 8,828,427 generally • File History of U.S. Patent No. 8,828,427 **Extrinsic Evidence:** • Celgene may rely on the expert opinion regarding the understanding of this term to	**Proposal & Evidence of Teva, Mylan, Breckenridge, and Aurobindo:** "total weight of the composition including the weights of counter ions and solvent molecules, if present" **Evidence** **Claims ('427 patent):** • Claims 1, 3, 5, 7, 9 and 11 **Specification ('427 patent):**

[17] Teva, Mylan, Breckenridge, and Aurobindo respectfully submit that Celgene has failed to disclose a proposed construction for this term in this Joint Statement or with its Local Patent Rule 4.2(a) disclosure. Teva, Mylan, Breckenridge, and Aurobindo thus reserve the right to seek relief from the Court on this issue, and may seek to preclude Celgene from offering a "plain and ordinary" meaning of the term. To the extent Celgene is able to propose a construction, Teva, Mylan, Breckenridge, and Aurobindo also reserve the right to seek to rely on additional evidence in opposition.

[18] Celgene has not "failed to disclose a proposed construction." Courts, including this one, routinely hold that no construction is required for claim terms. Notably, two Defendants—Apotex and Hetero—agree with Celgene that no construction is required for this term.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	• 2:39–3:3, 4:4–14, 4:47–5:18, 5:62–6:27, 7:26–50, 8:3–12:14, 19:57–67, 20:10–22:22, Examples 1–6 **Prosecution History ('427 Patent):** • Application as filed, May 19, 2010, *see, e.g.* 44–48 (claims 1, 11, 21, 31, 41, 51) • Office Action, April 24, 2012, *see, e.g.* at 3 • Amendment and Response, August 16, 2012, *see, e.g.* at 8 • Office Action, November 15, 2012, *see, e.g.* at 4–15 • Amendment and Response, February 13, 2013, *see, e.g.* at 7–8 & Ex. A • Advisory Action, March 25, 2013, *see, e.g.* at 2 • Interview Summary, May 16, 2013 • Supplemental Amendment and Response, June 17, 2013, *see, e.g.* at 2–4, 7 • Notice of Allowability, May 5, 2014, *see, e.g.* at 3–4 **Additional Evidence:** • McNally et al. (U.S. Patent No. 5,593,696). DEFS_POM_00013798–802 • Remington's Pharmaceutical Sciences, 17th Edition, Published 1985. CELPOM00001657–67

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		• Zeldis et al. (Pub. No. US 2007/0155791 Al, Published July 5, 2007). CELPOM00001573–623 • United States Pharmacopeia 31, National Formulary 26 (2008). DEFS_POM_00013803–816 • Pharmaceutical Calculations, 13th Ed. (2010). DEFS_POM_00013788–97 • Expert testimony from Dr. Kinam Park and/or similarly qualified experts establishing: (1) that a POSA would understand the claims to have Defendants' proposed construction; (2) that a POSA would understand the claims, specification and file history to support Defendants' proposed construction; (3) that a POSA understood the impact on the weight of a composition as a result of an active pharmaceutical ingredient being present as a salt or solvate; and (4) that standard practice in the field at the relevant time period was to calculate weights of compounds, including salt and solvates, taking into account counter ions and solvent molecules. Such testimony may be provided by an expert qualified in the field of pharmaceutical formulation and chemistry. **Proposal of Defendants Apotex and Hetero:** No construction necessary.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
"prescription approval code"	a code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable **Evidence** **Intrinsic Evidence:** • U.S. Patent No. 6,315,720 generally, including (without limitation) at 13:42-64, 14:67-15:6, 16:17-29[19] • File History of U.S. Patent No. 6,045,720 generally, including at Paper No. 4 (3/28/01 Response to Office Action), Paper No. 5 (4/18/01 Office Action), Paper No. 6 (6/25/01 Response to Office Action) **Extrinsic Evidence:** • IPR2015-1096, IPR2015-01102, IPR2015-01103 • Chambers 20th Century Dictionary (New ed. 1983) at 59, 243-244 • Random House Webster's College Dictionary (1991) at 68, 262 • Merriam Webster's Collegiate Dictionary (10th	Code representing consent to fill a prescription. **Evidence** • All intrinsic and extrinsic evidence cited by Celgene for this term in its Local Patent Rule 4.2(a)/4.2(b) and Local Rule 4.2(c) papers. **Intrinsic Evidence:** • '720 patent specification2, including: o Claims, col. 13:42-64, col. 14:67-col. 15:6, col. 16:17-33; • Prosecution File History ("FH"): o '720 patent FH 03/23/2001 Amendment, including at 2-5 o '720 patent FH 06/25/2001 Response and Amendment, including at 2, 4, 6 o '977 patent FH o '784 patent FH 07/18/2003 Preliminary Amendment, including at 2-3, 6-7 o '784 patent FH 07/29/2003 Supplemental Preliminary Amendment, including at 2-3 o '784 patent FH 10/20/2003 Reasons for

[19] U.S. Patent Nos. 6,315,720, 6,561,977, 6,755,784, 8,626,531, and 8,315,886 share a common specification. For convenience, citations to the specification are listed only for the '720 patent. Celgene relies on corresponding citations to the specifications of the '977, '784, '531, and the '886 patents.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	ed. 1998) at 57, 221 • Merriam Webster's Collegiate Dictionary (11th ed. 2003) at 61, 239 • Webster's Third New International Dictionary Unabridged, Merriam Webster, Inc. (1993) at 106, 437 • Celgene may rely on the expert opinion regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	Allowance, including at 2 o '399 patent FH 09/22/2004 Notice of Allowability, including at 2 o '399 patent FH 12/10/2004 Amendment after Allowance, including at 2-3 o '399 patent FH 02/02/2005 Comments on Statement of Reasons for Allowance, including at 2 o '018 patent FH 01/03/2005 Preliminary Amendment, including 3-4 o '018 patent FH 02/02/2006 Reply, including at 2-3 o '018 patent FH 02/21/2006 Supplemental Reply, including at 2-3 o '018 patent FH 03/15/2006 Reason for Allowance, including at 2 o '018 patent FH 05/19/2006 Comments on Statement of Reasons for Allowance, including at 2 o '566 patent FH 05/19/2006 Preliminary Amendment, including at 3-4 o '566 patent FH10/02/2007 Preliminary Amendment, including at 2-4, 6, 8 o '566 patent FH 07/09/2008 Reply, including at 3-9, 12-13 o '566 patent FH 10/14/2008

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		Supplemental Reply, including at 3-9 o '566 patent FH 01/08/2009 Office Action, including at 3, 5 o '566 patent FH 06/29/2009 Reply, including at 2-8, 10 o '566 patent FH 01/19/2010 Reply, including at 2-8 o '566 patent FH 05/06/2010 Supplemental Reply, including at 2-3 o '566 patent FH 08/12/2010 Office Action, including at 2-4 o '566 patent FH 11/09/2010 Reply, including at 2-4, 6-8 o '566 patent FH 11/19/2010 Office Action, including at 3-6 o '566 patent FH 02/25/2011 Reply, including 2, 5-6 o '886 patent FH 07/13/2012 Preliminary Amendment, including at 2-3 o '886 patent FH 07/17/2012 Notice of Allowability, including at 2-3 o '886 patent FH 9/21/2012 Supplemental Notice of Allowability, including at 2-3 o '531 patent FH 07/31/2013 Reply, including at 2-4, 6, 8-9; • *Coalition for Affordable Drugs v. Celgene*

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		Corp., IPR2015-01102, Paper Nos. 74, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 71, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 72 and 73, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489]; 1 (April 23, 2015) [DEFS-REMS00002930-2998]; 12 (July 29, 2015) [DEFSREMS00002533-2598]; 21 (October 27, 2015) [DEFS-REMS00001992-2017]: 42 at 20-24 (February 12, 2016) [DEFS-REMS00002730-2795]; 53 at 6-9 (May 27, 2016) [DEFS-REMS00003099-3129]; 75 at 12-16 (October 26, 2016) [DEFSREMS00002100-2137]; 78 (September 8, 2017) [DEFS-REMS00001954-1960] • *Coalition for Affordable Drugs v. Celgene Corp*., IPR2015-01092, Paper Nos. 72, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 69, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 70 and 71, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • *Coalition for Affordable Drugs v. Celgene Corp*., IPR2015-01096, Paper Nos. 72, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 69, Patent Owner

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 70 and 71, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489]; 1 (April 23, 2015) [DEFS-REMS00002862-2929]; 12 (July 30, 2015) [DEFS-REMS00002465-2532]; 21 (October 27, 2015) [DEFS-REMS00001968-1991]; 41 at 20-24 (February 12, 2016) [DEFS-REMS00002665-2729]; 51 at 8-12 (May 27, 2016) [DEFS-REMS00003068-3098]; 73 at 12-15 (October 26, 2016) [DEFSREMS00002064-2099]; 76 (September 8, 2017) [DEFS-REMS00001961-1967] • *Coalition for Affordable Drugs v. Celgene Corp*., IPR2015-01103, Paper No. 75, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 72, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 73 and 74, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489]; 1 (April 23, 2015) [DEFS-REMS00002999-3067], 12 (July 28, 2015) [DEFS-REMS00002599-2664], 22 (October 27, 2015) [DEFS-REMS00002018-2043], 43 at 20-24 (February 12, 2016) [DEFS-REMS00002796-2861], 54 at 6-9 (May 27, 2016) [DEFS-REMS00003130-3160], 76 at 12-16 (October 26, 2016) [DEFS-REMS00002138-2175], 79 (September 8, 2017) [DEFS-

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		REMS00001947-1953] • Celgene's Opening Appeal Brief in appeal of PTAB's Final Written Decision (CAFC-18-1167, -1168, -1169), and all relevant subsequent papers filed in the appeal [DEFS-REMS00001739-1946]; • File Histories for European Equivalents to the REMS Patents-in-Suit [DEFSREMS00003633-DEFS-REMS00004355], including without limitation File History for EP Application No. 00976627.0 at June 8, 2006 Communication from the Examining Division, October 8, 2016 Celgene Letter, and February 1, 2008 Summons to attend oral proceedings. **Extrinsic Evidence:** • *Celgene Corp. v. Natco Pharma Ltd.*, 2:10-cv-05197 (D.N.J. 2016), Dkt. Nos. 81, 85, 86, 111, 113, and 206 [DEFS-REMS00002253-2464]; • *Celgene Corp. v. Lotus Pharm. Co. Ltd.*, 2:17-cv-06842 (D.N.J. 2018), Dkt. Nos. 72, 74 [DEFS-REMS00003291-DEFS-REMS00003292, DEFS-REMS00003293-DEFSREMS00003294] • Defendants may present expert testimony from a pharmacist or person having experience with risk management relating to pharmaceutical products as to the meaning of this term to a person of ordinary skill in the art based on the

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		specification, prosecution history and extrinsic evidence cited by the parties, as well as the expert's knowledge and experience. In particular, the expert may testify that the term "prescription approval code" does not require that "an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable", as the PTAB held in the IPRs involving the '720 patent.
"computer readable storage medium"	a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and patients **Evidence** **Intrinsic Evidence:** • U.S. Patent No. 6,315,720 generally, including (without limitation) at Abstract, 1:64-2:12, 2:49-59, 4:43-6:10, 8:27-38, 13:18-32 • U.S. Patent No. 6,045,501 generally, including (without limitation) at Abstract, 2:9-63, 4:10-13, 4:50-57, 5:24-33, 5:55-58, 10:43-67 • File History of United States Patent No. 6,045,501 at Paper No. 5 (10/7/99 Office Action), Paper No.	No construction necessary, but if construed, should be construed to have its plain and ordinary meaning, which is "computer readable storage medium, which may or may not be centralized." **Evidence:** • All intrinsic and extrinsic evidence cited by Celgene for this term in its Local Patent Rule 4.2(a)/4.2(b) and Local Rule 4.2(c) papers. **Intrinsic Evidence:** • **'720 patent specification[20], including:** o Claims, Abstract, col. 2:1-8, col. 2:50-60, col. 4:43-col. 6:3, col. 6:22-29, col. 6:37-44, col. 7:24-29, col. 8:20-38, col. 10:30-35, col. 11:32-38, col. 12:20-26,

[20] The Williams patents are related patents that share a common specification. For convenience, citations to the specification are listed only for the '720 patent. REMS Defendants rely on corresponding citations to the specifications of the other Williams patents.

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	6 (11/10/99 Reply to Office Action) **Extrinsic Evidence:** • Celgene may rely on the expert opinion regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	col. 13:27-39, col. 13:45-54, col. 14:15-36, col. 14:54-56, col. 14-67-col. 15:3, col. 15:47-52, col. 16:10-29, col. 17:58-66; • **Prosecution File History ("FH"):** o '720 patent FH 01/18/2001 Office Action, including at 2 o '720 patent FH 03/23/2001 Amendment, including at 2, 4-5, 6 o '720 patent FH 04/18/2001 Office Action, including at 2 o '720 patent FH 06/25/2001 Response and Amendment, including at 2-3, 6 o '977 patent FH 04/09/2013 Application for Extension of Patent Term, including at 5 o '784 patent FH 07/18/2003 Preliminary Amendment, including at 2-3, 7 o '784 patent FH 07/29/2003 Supplemental Preliminary Amendment, including at 2-3 o U.S. Patent No. 6,869,399 (Application No. 10/762,880) FH [DEFS-REMS00000564-804] o '399 patent FH 09/22/2004 Notice of Allowability, including at 2

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		o '399 patent FH 12/10/2004 Amendment after Allowance, including at 2-5 o '399 patent FH 02/02/2005 Comments on Statement of Reasons for Allowance, including at 2 o U.S. Patent No. 7,141,018 (Application No. 11/028,144) FH [DEFS-REMS00000314-563] o '018 patent FH 01/03/2005 Preliminary Amendment, including 3-4 o '018 patent FH 02/02/2006 Reply, including at 2-3 o '018 patent FH 02/21/2006 Supplemental Reply, including at 2-3 o '018 patent FH 05/19/2006 Comments on Statement of Reasons for Allowance, including at 2 o U.S. Patent No. 7.959,566 (Application No. 11/437,551) FH [DEFS-REMS00001213-1626] o '566 patent FH 10/02/2007 Preliminary Amendment, including at 3, 5-8 o '566 patent FH 07/09/2008 Reply, including at 4, 6-9 o '566 patent FH 10/14/2008 Supplemental Reply, including at 4, 6-9 o '566 patent FH 06/29/2009 Reply,

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		including at 3, 5-8 o '566 patent FH 01/19/2010 Reply, including at 3, 5-8 o '566 patent FH 05/06/2010 Supplemental Reply, including at 2-3 o '566 patent FH 08/12/2010 Office Action, including at 3 o '566 patent FH 11/9/2010 Reply, including at 2-3, 5-7 o '566 patent FH 11/19/2010 Office Action, including at 3-4 o '566 patent FH 02/25/2011 Reply, including at 2, 5-6 o U.S. Patent No. 8,315,886 (Application No. 12/966,261) FH 07/13/2012 Preliminary Amendment, including at 2-3 o '886 patent FH 07/17/2012 Notice of Allowability, including at 2-3 o '886 patent FH 09/21/2012 Supplemental Notice of Allowability, including at 2-3; • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01102, Paper Nos. 74, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 71, Patent Owner Demonstratives (July 19, 2016) [DEFS-

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		REMS00003490-DEFSREMS00003529]; 72 and 73, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01092, Paper Nos. 72, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 69, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 70 and 71, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489]; 1 (April 23, 2015) [DEFS-REMS00001113-1180]; 10 (July 28, 2015) [DEFS-REMS00000986-1046]; 20 (October 27, 2015) [DEFS-REMS00000969-985]; 40 at 20-25 (February 12, 2016) [DEFS-REMS00001047-1112]; 49 at 7-9 (May 27, 2016) [DEFS-REMS00001181-1212]; 73 at 9-11 (October 26, 2016) [DEFS-REMS00000934-968]; 76 (September 8, 2017) [DEFS-REMS00000805-810]; Exhibit 1004 at CFAD VI 1004-0032 - CFAD VI 1004-0034, CFAD VI 1004-0061 - CFAD VI 1004-0064, and CFAD VI 1004-0074 - CFAD VI 1004-0080 (April 23, 2015) [DEFS-REMS00000811-933] • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01096, Paper Nos. 72, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 69, Patent Owner

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 70 and 71, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01103, Paper No. 75, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 72, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 73 and 74, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • Celgene's Opening Appeal Brief in appeal of PTAB's Final Written Decision (CAFC-18-1171), and all relevant subsequent papers filed in the appeal [DEFS-REMS00001627-1738]; • File Histories for European Equivalents to the REMS Patents-in-Suit [DEFSREMS00003633-DEFS-REMS00004355], including without limitation File History for EP Application No. 10006197.7 at April 3, 2012 Letter from Celgene, May 3, 2013 Letter from Celgene, and July 2, 2013 Summons to attend oral proceedings **Extrinsic Evidence:** • *Celgene Corp. v. Lotus Pharm. Co. Ltd.*, 2:17-cv-06842 (D.N.J. 2018), Dkt. Nos. 72, 74

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		[DEFS-REMS00003291-DEFS-REMS00003292, DEFS-REMS00003293-DEFSREMS00003294] • Defendants may present expert testimony from a pharmacist or person having experience with risk management relating to pharmaceutical products as to the meaning of this term to a person of ordinary skill in the art based on the specification, prosecution history and extrinsic evidence cited by the parties, as well as the expert's knowledge and experience. In particular, the expert may testify that the plain and ordinary meaning of the term "computer readable storage medium" (in view of the specification and prosecution history) does not require that the "computer readable storage medium" be centralized.
"computer readable medium"	"a centralized database that includes all registration information regarding the claimed prescribers, pharmacies, and patients" **Evidence** **Intrinsic Evidence:** • U.S. Patent No. 8,626,531 generally, including (without limitation) at Abstract, 2:14-28, 2:66-3:20, 4:59-6:56; 8:37-47, 13:18-40 • U.S. Patent No. 6,045,501 generally, including (without limitation) at Abstract, 2:9-63, 4:10-13, 4:50-57, 5:24-33, 5:55-58, 10:43-67	No construction necessary, but if construed, should be construed to have its plain and ordinary meaning, which is "computer readable medium, which may or may not be centralized." **Evidence** • All intrinsic and extrinsic evidence cited by Celgene for this term in its Local Patent Rule 4.2(a)/4.2(b) and Local Rule 4.2(c) papers. **Intrinsic Evidence:** • **'531 patent specification, including:**

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	• File History of U.S. Patent No. 6,045,501 at Paper No. 5 (10/7/99 Office Action), Paper No. 6 (11/10/99 Reply to Office Action) **Extrinsic Evidence:** • Celgene may rely on the expert opinion regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	o Claims, Abstract, col. 13:41-44, col. 13:32-38, col. 2:66-3:9, col. 4:59-6:50, col. 7:35-39, col. 8:42-46, col. 10:34-36, col. 11:33-39, col. 12:20-26, col. 13:22-32, col. 14:13-33, col. 14:63-67, col. 15:42-46, col. 16:4-18, col. 17:51-58; • **Prosecution File History ("FH"):** o '720 patent FH o '977 patent FH o '784 patent FH o '399 patent FH o '018 patent FH o '566 patent FH 10/02/2007 Preliminary Amendment, including at 2 o '566 patent FH 05/01/2008 Office Action, including at 5 o '566 patent FH 07/09/2008 Reply, including at 3 o '566 patent FH 01/08/2009 Office Action, including at 2 o '566 patent FH 08/12/2010 Office Action, including at 3-4 o '566 patent FH 11/9/2010 Reply, including at 6 o '566 patent FH 11/19/2010 Office

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		Action, including at 3-6 o '566 patent FH 02/25/2011 Reply, including at 5 o '886 patent FH o '531 patent FH 05/02/2013 Office Action, including at 3 o '531 patent FH 07/31/2013 Reply, including at 2-9; • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01102, Paper Nos. 74, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 71, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 72 and 73, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01092, Paper Nos. 72, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 69, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 70 and 71, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489]; 1 (April 23, 2015) [DEFS-REMS00001113-1180]; 10 (July 28, 2015) [DEFS-REMS00000986-1046]; 20 (October 27, 2015) [DEFS-REMS00000969-985]; 40 at 20-

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		25 (February 12, 2016) [DEFS-REMS00001047-1112]; 49 at 7-9 (May 27, 2016) [DEFS-REMS00001181-1212]; 73 at 9-11 (October 26, 2016) [DEFS-REMS00000934-968]; 76 (September 8, 2017) [DEFS-REMS00000805-810]; Exhibit 1004 at CFAD VI 1004-0032 - CFAD VI 1004-0034, CFAD VI 1004-0061 - CFAD VI 1004-0064, and CFAD VI 1004-0074 - CFAD VI 1004-0080 (April 23, 2015) [DEFS-REMS00000811-933] • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01096, Paper Nos. 72, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 69, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 70 and 71, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • *Coalition for Affordable Drugs v. Celgene Corp.*, IPR2015-01103, Paper No. 75, (September 12, 2016) [DEFS-REMS00003530-DEFS-REMS00003632]; 72, Patent Owner Demonstratives (July 19, 2016) [DEFS-REMS00003490-DEFSREMS00003529]; 73 and 74, Petitioner's Demonstrative Exhibits (July 19, 2016) [DEFS-REMS00003295-DEFS-REMS00003489] • File Histories for European Equivalents to the REMS Patents-in-Suit [DEFSREMS00003633-

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		DEFS-REMS00004355], including without limitation File History for EP Application No. 10006197.7 at April 3, 2012 Letter from Celgene, May 3, 2013 Letter from Celgene, and July 2, 2013 Summons to attend oral proceedings • Celgene's Opening Appeal Brief in appeal of PTAB's Final Written Decision (CAFC-18-1171), and all relevant subsequent papers filed in the appeal [DEFS-REMS00001627-1738]; **Extrinsic Evidence:** • U.S. Patent No. 6,045,501: o Claims, col. 2:10-62, col. 4:10-col. 5:64, col. 8:25-32, col. 9:15-21, col. 10:20-27 [DEFS-REMS00003161-3167]; • *Celgene Corp. v. Lotus Pharm. Co. Ltd.*, 2:17-cv-06842 (D.N.J. 2018), Dkt. Nos. 72, 74 [DEFS-REMS00003291-DEFS-REMS00003292, DEFS-REMS00003293-DEFSREMS00003294] • Defendants may present expert testimony from a pharmacist or person having experience with risk management relating to pharmaceutical products as to the meaning of this term to a person of ordinary skill in the art based on the specification, prosecution history and extrinsic evidence cited by the parties, as well as the expert's knowledge and experience. In particular, the expert may testify that the plain

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
		and ordinary meaning of the term "computer readable medium" (in view of the specification and prosecution history) does not require that the "computer readable medium" be centralized.

"a generator configured to generate a prescription approval code"	"prescription approval code" means "a code representing that an affirmative risk assessment has been made based upon risk-group assignment and the information collected from the patient, and that is generated only upon a determination that the risk of a side effect occurring is acceptable"
	
	No construction necessary for remainder of proposed language
	
	Evidence
	
	Intrinsic Evidence:
	
	• U.S. Patent No. 8,626,531 generally, including (without limitation) at 13:41-67, 14:56-15:3, 16:11-24
	
	• File history of U.S. Patent No. 8,626,531
	
	• U.S. Patent No. 6,315,720 generally, including (without limitation) at 13:42-64, 14:67-15:6, 16:17-29
	
	• File history of U.S. Patent No. 6,315,720 at Paper No. 4 (3/28/01 Response to Office Action), Paper No. 5 (4/18/01 Office Action), Paper No. 6 (6/25/01 Response to Office Action)
		Indefinite
		
		Evidence
		
		• All intrinsic and extrinsic evidence cited by Celgene for this term in its Local Patent Rule 4.2(a)/4.2(b) and Local Rule 4.2(c) papers.
		
		Intrinsic Evidence:
		
		• **'531 patent specification, including:**
		
		  • Claims, col. 6:18-23, col. 13:48-53, col. 14:63-67, col. 16:18-34, col. 17:51-col. 18:2;
		
		• **Prosecution File History ("FH"):**
		
		  o '720 patent FH
		  o '977 patent FH
		  o '784 patent FH
		  o '399 patent FH
		  o '018 patent FH
		  o '566 patent FH
		  o '886 patent FH
		  o '531 patent FH 07/31/2013 Reply,

Claim Term	Celgene's Proposal & Evidence	Defendants' Proposal & Evidence
	Extrinsic Evidence: • IPR2015-1096, IPR2015-01102, IPR2015-01103 • Chambers 20th Century Dictionary (New ed. 1983) at 59, 243-244, 522 • Random House Webster's College Dictionary (1991) at 68, 262, 555 • Merriam Webster's Collegiate Dictionary (10th ed. 1998) at 57, 221, 484 • Merriam Webster's Collegiate Dictionary (11th ed. 2003) at 61, 239, 521 • Webster's Third New International Dictionary Unabridged, Merriam Webster, Inc. (1993) at 106, 437, 945 • Celgene may rely on the expert opinion regarding the understanding of this term to ordinarily skilled artisans at the time the patents-in-suit were filed. The expert(s) may also opine regarding the level of ordinary skill in the art and/or the qualifications of one of ordinary skill in the art. The expert(s) may also provide opinions to rebut the opinions of Defendants' expert(s).	including at 2; **Extrinsic Evidence:** • *Celgene Corp. v. Lotus Pharm. Co. Ltd.*, 2:17-cv-06842 (D.N.J. 2018), Dkt. Nos. 72, 74 [DEFS-REMS00003291-DEFS-REMS00003292, DEFS-REMS00003293-DEFSREMS00003294] • Defendants may present expert testimony from a pharmacist or person having experience with risk management relating to pharmaceutical products that this term is indefinite to a person of ordinary skill in the art based on the specification, prosecution history and extrinsic evidence cited by the parties, as well as the expert's knowledge and experience. In particular, the expert may testify that (a) the term "generator" does not have a sufficiently definite meaning as the name for a structure, but rather is simply another way of saying "means for generating", and (b) the function recited in the term is "generating a prescription approval code," and (c) the specification does not clearly link or associate a structure with performing the function of "generating a prescription approval code."